


**LETTER OF INFORMATION & CONSENT TO
PARTICIPATE IN A RESEARCH STUDY**



- ☐ **Study Title:**
- ☐ **Principal Investigator:**
- ☐ **Co-Investigators:**
- ☐ **Study Coordinator and/or 24 Hour Contact:**
- ☐ **Study Sponsor:**
- ☐ **Conflict of Interest:**
<< DOES(DO) THE INVESTIGATOR(S) HAVE ANY CONFLICTS OF
INTEREST?>>
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- ☐ **INTRODUCTION**
<<INFORMED CONSENT/INTRODUCTION >>
- ☐ **BACKGROUND AND PURPOSE OF THE RESEARCH**
<< WHAT IS THE USUAL TREATMENT?>>
<<WHY IS THE STUDY BEING DONE >>
- ☐ **DESCRIPTION OF THE RESEARCH/STUDY
VISITS/PROCEDURES**
<< WHAT WILL HAPPEN DURING THIS STUDY?>>
<< HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?>>
<< WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?>>
- ☐ **POTENTIAL HARMS** ☐ **REPRODUCTIVE RISKS**
<<WHAT ARE THE POTENTIAL RISKS OR HARMS OF PARTICIPATING
IN THIS STUDY>>
- ☐ **POTENTIAL BENEFITS**
<<WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?>>
- ☐ **ALTERNATIVES TO PARTICIPATION**
<< WHAT OTHER CHOICES ARE THERE?>>
- ☐ **PRIVACY and CONFIDENTIALITY**
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>
- ☐ **COMMUNICATION WITH PRIMARY CARE OR TREATING DOCTOR**
<< COMMUNICATION WITH YOUR FAMILY DOCTOR>>
- ☐ **COSTS TO PARTICIPATION AND/OR REIMBURSEMENT**
<< WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?>>
<<ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS
STUDY?>>

☐ **IN CASE OF INJURY, ILLNESS or HARM**
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>

☐ **PARTICIPATION AND WITHDRAWAL**
<< CAN PARTICIPATION IN THIS STUDY END EARLY? >>
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>

☐ **NEW FINDINGS OR INFORMATION**
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>

☐ **STUDY RESULTS**

☐ **STUDY CONTACT**
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>

☐ **REB CONTACT**
<< WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY? >>

☐ **STATEMENT OF CONSENT**
<<Signature(s)>>